UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 22, 2017

ZOGENIX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-34962**	**20-5300780**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5858 Horton Street, #455, Emeryville, CA	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 550-8300

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933(§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On June 22, 2017, Zogenix, Inc. (the "Company") announced that the U.S. Food & Drug Administration ("FDA") has granted its investigational drug, ZX008 (low-dose fenfluramine), orphan drug designation for the treatment of Lennox Gastaut Syndrome ("LGS"), a refractory, debilitating childhood-onset epilepsy. The Orphan Drug Designation by the FDA follows the European Union's European Medical Agency grant of Orphan Drug Designation for ZX008 in the treatment of LGS earlier this year.

The Company intends to initiate the Phase 3 clinical trial in LGS in the second half of 2017, following the availability of top-line Phase 3 data in our initial indication, Dravet syndrome. The Company expects that the first patients will enroll in the planned LGS study in the fourth quarter of 2017. The Company is conducting a Phase 3 program in the U.S. and internationally for ZX008 in Dravet syndrome. The last patient in the Company's first Phase 3 pivotal study in Dravet syndrome was randomized in April 2017, and top-line data are expected in the third quarter of 2017. ZX008 for the treatment of Dravet syndrome has orphan designation in both the United States and Europe, and the development program has received Fast Track designation in the United States.

***

The Company cautions you that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding ZX008's potential as a treatment for seizures associated with LGS and Dravet syndrome; the timing of the initiation the Phase 3 clinical trial in LGS; the timing of top line results for the on-going Phase 3 clinical trials in Dravet syndrome; and the expected benefits associated with orphan drug designation. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in the Company's business, including, without limitation: risks that the benefits associated with orphan drug designation may not be realized, including that orphan drug exclusivity may not effectively protect a product from competition and that such exclusivity may not be maintained; the uncertainties associated with the clinical development and regulatory approval of product candidates such as ZX008, including potential delays in the commencement, enrollment and completion of clinical trials; the potential that earlier clinical trials and studies may not be predictive of future results; top-line data from the Phase 3 clinical trials of ZX008 in Dravet syndrome may not support our NDA for ZX008 in Dravet syndrome; negative top-line data from the ongoing Phase 3 clinical trials may delay or prevent commencement of the Phase 3 clinical trial in LGS; the Company's reliance on third parties to conduct its clinical trials, enroll patients, manufacture its preclinical and clinical drug supplies and manufacture commercial supplies of its drug products, if approved; unexpected adverse side effects or inadequate therapeutic efficacy of ZX008 that could limit approval and/or commercialization, or that could result in recalls or product liability claims; the Company's ability to fully comply with numerous federal, state and local laws and regulatory requirements, as well as rules and regulations outside the United States, that apply to its product development activities; Fast Track designation may not result in an expedited regulatory review process; the potential for distraction of management related to the transition of management responsibilities; and other risks described in the Company's prior public periodic filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZOGENIX, INC.

Date: June 22, 2017

By: /s/ Michael P. Smith
Name: Michael P. Smith
Title: Executive Vice President, Chief Financial Officer, Treasurer and Secretary